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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,016	03/16/2005	Kazuhiro Matsumoto	2114-0113PUS1	9503

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EXAMINER
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HOFFMAN, SUSAN COE

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,016	<b>Applicant(s)</b> MATSUMOTO ET AL.	
	<b>Examiner</b> Susan Coe Hoffman	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 8-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 8-17 are currently pending.

#### ***Election/Restrictions***

2. Applicant's election with traverse of Toki-shakuyaku-san in the reply filed on June 15, 2006 is acknowledged. The traversal is on the ground(s) that all of the species share the same common features because they are all types of Kampo medicine. This is not found persuasive because Kampo is defined by applicant on page 1 of the specification as being any type of botanical extract. Thus, the term "Kampo medicine" is considered to encompass thousands of different compositions. In addition, the specific species claimed by applicant all have different ingredients. Thus, since the ingredients are different, the species cannot be considered to have the same structural elements.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 8-17 are examined on the merits solely in regards to the elected species.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what types of medicines are encompassed by "Kampo medicines;" thus, the metes and bounds of the claims are unclear.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8, 10, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,318,798 in view of JP 61033122 A and JP 11060504.

US '798 teaches that the pharmaceutical effects of Kampo medicines such as toki-shakuyaku-san cannot be achieved unless the medicine is formulated in a manner that allows for the dissolution of the medicine (see abstract and columns 1-3). Thus, the reference teaches that it was known in the art at the time of the invention that the manner in which Kampo medicines are formulated is important for the pharmaceutical effects of the medicines. However, the reference does not specifically teach using cellulose glycolate or sodium hydrogen carbonate during the formulation of the toki-shakuyaku-san.

JP '122 teaches using cellulose glycolate to formulate tablets. The reference teaches that the tablets have improved disintegration characteristics (see English abstract).

JP '504 teaches using sodium bicarbonate (synonymous with sodium hydrogen carbonate) to formulate tablets. The reference teaches that the tablets have improved disintegration characteristics (see English abstract).

Thus, it was known in art at the time of the invention that using cellulose glycolate and sodium hydrogen carbonate to formulate tablets improves the properties of the tableted pharmaceutical product because it allows for the better disintegration of the product. Therefore,

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a person of ordinary skill in the art would reasonably expect that using cellulose glycolate and sodium hydrogen carbonate to create a tablet with the active ingredient toki-shakuyaku-san would make an improved pharmaceutical product. This is especially true in light of the teaching of US '798 that the ability of the toki-shakuyaku-san to be dissolved in the body is essential to the ability of this medicine to function successfully. Therefore, this reasonable expectation of success would have provided motivation for a person of ordinary skill in the art to formulate toki-shakuyaku-san into a tablet with cellulose glycolate and sodium hydrogen carbonate.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

6. Claims 9, 11, 13, 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,318,798 in view of JP 61033122 A and JP 11060504 as applied to claims 8, 10, 12, and 15 above, and further in view of JP 56152416 A.

As discussed above, the combination of US '798, JP '122 and JP '504 is considered to teach a tableted composition comprising toki-shakuyaku-san, cellulose glycolate and sodium hydrogen carbonate. However, the references do not specifically teach using silicic anhydride in the tablet.

JP '416 teaches creating a tablet that has improved disintegration and dissolution. The tablet is made by dispersing an herbal remedy in a silicic acid anhydride solution to create a powdered or granulated mixture. This mixture is then added to suitable excipients or lubricants to create a tablet (see English abstract). Thus, a person of ordinary skill in the art would reasonably expect that using this step prior to the addition of cellulose glycolate and sodium hydrogen carbonate to the toki-shakuyaku-san would produce a tablet with improved dissolution and disintegration. This reasonable expectation of improved results would motivate the artisan of ordinary skill to modify the references in this manner.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected

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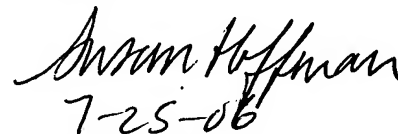
results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



7-25-06

Susan Coe Hoffman  
Primary Examiner  
Art Unit 1655